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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/499,423	07/07/1995	CAREY V. CAMPBELL	MP/84	2478
28596 7590 12/11/2008 GORE ENTERPRISE HOLDINGS, INC. 551 PAPER MILL ROAD P. O. BOX 9206 NEWARK, DE 19714-9206				
EXAMINER				
PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
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12/11/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

08/499,423

Applicant(s)

CAMPBELL ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,10,14-33,35,118 and 119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,10,14-33,35,118 and 119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/25/08 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that the article is "non-elastomeric" was not found in the written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3-7,9,10,14-31,119 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 119 recite the new limitation that the article is "non-elastomeric". However, the specification does not describe or even use the term to define what defines a "non-elastomeric" device or apparatus. Without a description to define limits and boundaries to define what defines an elastomeric article as compared to what a "non-elastomeric" article, a person of ordinary skill cannot determine specific differences.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-7,9,10,14-31,119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As best understood if something is "non-elastomeric" as recited in claims 1,119 then according to known properties, it should not change or be resilient. However, claims 1 and 119 recite that the article has its circumference increase in response to internal pressures. Therefore there is a contradiction because if the tube increases in circumference dimensions, it then would appear to be elastomeric. As a result there is ambiguity as to how the article is "non-elastomeric", but yet it can change its circumference.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5,9,10,14,17,19,20,22-31,33,35,119 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (5061276). Tu et al. disclose (col. 12, lines 20,21) a tube with an outer covering, Fig. 2. Tu also discloses the device can be used as a graft, col. 4, lines 53-55. Tu additionally discloses the tube is "essentially" porous, col. 3, lines 4-6. Tu discloses the graft tube is made of polytetrafluoroethylene and has a covering of "essentially" polytetrafluoroethylene, col. 3, lines 45,46. Tu et al. disclose the graft can be sutured to a conduit, col. 5, lines 55-63. Tu also discloses the graft circumference increases as a result of the blood pressure, col. 5, lines 46-48. Tu additionally discloses the tube can be expanded such that the second circumference (10mm) is at least 100% larger than the tube's original circumference (4mm) prior to the application of internal pressure, col. 10, lines 34-38. The polytetrafluoroethylene tube is disclosed as having a microstructure of nodes interconnected by fibrils, col. 7, lines 19-22. The circumference is fully capable of being increased by inflating a balloon. Tu also discloses the tube is placed on a tapered mandrel such that it forms a tapered end with a larger circumference at one end and a smaller second circumference at an opposing end, col. 10, lines 33-35. Because the same materials as claimed are disclosed by the prior art, the examiner asserts that the claimed physical properties are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not

present in the prior art. Regarding claim 27, it can be construed that an interior liner is present on the graft when multiple layers of PTFE are used, col. 3, lines 35-38. As best understood with respect to the new limitation of "non-elastomeric" the tube made of PTFE is considered "non-elastomeric".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Eilentropp (4791966). Tu et al. is explained supra. Tu also discloses (col. 11, lines 7-11,col. 12, lines 1-4) that layers of film applied to the tube are helical. However, Tu et al. do not explicitly disclose the PTFE layers are helical. Eilentropp teaches (Fig. 5) that PTFE film (abstract) can be applied helically about a tube. Eilentropp also teaches that helically wrapping prevents leakage, col. 7, line 68, col. 8, lines 1-3. Therefore, it would have been obvious to one of ordinary skill in the art to apply the PTFE layers helically as taught by Eilentropp about the tube of Tu et al. such that it improves its compatibility and resistance to leakage.

Claims 18,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Hughes et al. (4728328). Tu et al. is explained supra. However, Tu does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the

prosthesis of Tu et al. in a vessel such as the trachea requiring replacement to the two bronchi.

Claims 3,4,15,16,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Lee (5123917). Tu et al. is explained as before. However, Tu fails to disclose the wall thickness to be less than 0.1mm or use of a stent used to secure the graft to a conduit. Lee teaches that the thickness of the graft equal to about 0.1mm, col. 5, lines 56-59. Lee additionally teaches (col. 5, lines 25-31) a stent is used to secure a graft to a blood conduit, Figs. 1,4. Lee also teaches the stent is used to provide some stiffness to the graft to support the vessel, col. 3, lines 5-9,20-24. It would have been obvious to one of ordinary skill in the art to utilize a stent or stents as taught by Lee in the graft of Tu et al. such that it provides greater support to the vessel it is implanted in. Additionally, the use of a thickness of about 0.1mm for the wall of the graft as taught by Lee in the implant of Tu et al. provides a flexible and small profile for easier delivery to the implantation site.

Claim 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb (6436135) in view of Eilentropp (4791966). Goldfarb discloses a tube of PTFE (col. 3, lines 40-55) that is fully capable of having its circumference increase with blood pressure application. The prosthesis is for use as a vascular graft, col. 1, lines 3-5. However, Goldfarb does not explicitly disclose the PTFE layers applied on the tube. Eilentropp teaches (Fig. 5) that PTFE film (abstract) can be applied helically about a tube. Eilentropp also teaches that helically wrapping prevents leakage, col. 7, line 68, col. 8, lines 1-3. Therefore, it would have been obvious to one of ordinary skill in the art

to apply the PTFE layers helically as taught by Eilentropp about the tube of Goldfarb such that it improves its compatibility and resistance to leakage. The tube can increase up to 100% and the second circumference can remain "substantially unchanged" upon a variety of operating pressures.

Response to Arguments

Applicant's arguments filed 7/25/08 have been fully considered but they are not persuasive. Regarding Applicant's remarks about the Tu article comprising a tube that has an elastomeric layer, it must be noted that the claims use the transition phrase "comprising" which does not exclude elements not claimed. Thus, Applicant's arguments are moot with respect to this issue. Applicant also argues the Eilentropp teaching would not remedy the Tu deficiency. However, the Examiner is not persuaded since the disclosure fails to define what one of ordinary skill defines as "non-elastomeric" and thus there is a contradiction in the claims. Eilentropp would only improve the integrity of the tubes in which its ptfe layers are applied thereon.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738